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Toxic Substances Control Act (TSCA) Report to Congress for Fiscal Year 1982

U.S. Environmental Protection Agency
Office of Toxic Substances
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TSCA Annual Report for FY82

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NOTE: This Report to Congress summarizes progress made during Fiscal Year 1982 by the Environmental Protection Agency (EPA) in implementing the Toxic Substances Control Act (TSCA). It fulfills the congressional reporting requirements of the Act, including those contained in Sections 30, 9(d), and 28(c) of TSCA and reports on broader TSCA activities as well.

I. Introduction

The Toxic Substances Control Act (TSCA) took effect on January 1, 1977. It is a comprehensive piece of environmental legislation designed to fill gaps in protection among eighteen other environmental and public health laws. It is also a very complex piece of legislation: it seeks to prevent injury from harmful chemicals through a process of premanufacture notification for new chemicals (Section 5); to obtain more data on potential chemical hazards through authorities to require testing (Section 4) and reporting (Section 8); and to control unreasonable risks of existing chemicals through regulations (Sections 6 and 7). TSCA authorizes EPA to regulate against such risks at any stage in a chemical's life-cycle: manufacturing, processing, commercial distribution, use, and/or disposal.

TSCA is wholly consistent with the concept of controlling problems with minimal burdens (Executive Order 12291, the Regulatory Flexibility Act, and the Paperwork Reduction Act). Specifically, TSCA mandates that its authorities not impede or create unnecessary economic barriers to technological innovation and that reason and prudence be used in carrying out its responsibilities. To achieve a balanced approach, the Act requires a weighing of risks against benefits provided by particular chemicals to the nation's economic and social well-being.

Highlights of the Year

Program Implementation. The 1982 fiscal year was a dynamic period of TSCA implementation. The Agency completed several key projects, some of which have been in process for some time. These include major rulemaking actions on asbestos and PCBs; issuance of key information gathering rules to support chemical testing decisions, publication of nearly 100 testing guidelines, announcement of proposed exemption rules for selected new chemicals, and the completion of a number of negotiated agreements for chemical testing. Also during this period, the TSCA Inventory of Chemicals in Commerce was updated to include a current total of over 58,000 chemicals.

The Agency established firm priorities: first, to meet all statutory and court deadlines, second, to clean up Agency backlogs, and third, to reduce unnecessary regulatory burdens. In pursuing these priorities, the TSCA program reflected the Agency's commitment to high quality scientific analysis in carrying out its responsibilities to protect public health and the environment.

Regulatory Reform. A number of regulatory reform initiatives were implemented during FY'82. The changes may be characterized in terms of policy, regulatory, and administrative objectives. Policy reforms emphasize negotiated testing agreements wherever appropriate, allow flexibility to industry whenever possible, and encourage small business initiatives. The regulatory changes are designed to reduce unnecessary regulatory burdens, to provide for exemptions to requirements, and to focus controls and investigations on the more significant health and environmental problems. Administrative changes were instituted to meet legislative and judicial time schedules, to be more timely in responding to constituents, and to reduce work backlogs. As a result of these changes in FY'82, for the first time since TSCA became effective, the Agency met all statutory and court imposed deadlines for every section of the law.

Enforcement. Over the last year, three broad trends have developed in the regulatory philosophy of the compliance/enforcement program. They are (1) decreased emphasis on "adversarial enforcement" and more emphasis on technical assistance; (2) vigorous enforcement of serious violators; and (3) avoidance of unnecessarily burdensome restrictions on the regulated community.

TSCA compliance inspections and enforcement actions have flourished in this atmosphere and continue to increase. For example, in FY'82 compliance inspections were increased by just over 100 percent and administrative enforcement actions were over 30 percent higher than in FY'81. In contrast to FY'81 when EPA referred no potential criminal cases to the Department of Justice for consideration, in FY'82 EPA referred two cases. In addition, in September 1982 the Agency settled a major administrative civil penalty case under TSCA. American Cyanamid agreed to pay $18,750 in settlement of a complaint alledging violation of TSCA Section 8(e) by delaying submission to EPA of information indicating that a flame retardant chemical could pose substantial risks.

International Cooperation. International cooperation in chemical control activities is intended to promote the sharing of information among nations. This is needed to reduce duplication of effort in chemical testing and assessment, to provide better solutions to global environmental problems, and to avoid the creation of technical barriers to trade. During FY'82, in conjunction with its own responsibilities related to chemical testing and assessment, EPA continued to be actively involved in related work with many international organizations. In addition, EPA has made considerable progress in implementing the Mutual Acceptance of Data Decision in the U.S.

For example, the Agency participated in the work of the multi-national Chemicals Program of the Organization for Economic Cooperation and Development (OECD). EPA provided experts to work groups responsible for developing further OECD test guidelines, for updating previously adopted

guidelines, and for work under the Hazard Assessment Project. EPA was designated to head the U.S. delegation to the second High Level Meeting of the Chemicals Group. At this meeting, the Environmental Ministers of OECD nations will take action on and provide guidance for future work on implementation of OECD Principles of Good Laboratory Practice, information exchange between member nations, trial use of Data Interpretation Guides, and a recently begun OECD Existing Chemicals program.

EPA also participated extensively in the work of the United Nations Environment Program (UNEP) and the World Health Organization (WHO). The Agency provided experts to assist the UNEP/WHO International Program on Chemical Safety in their work on harmonizing risk assessment methodologies and to assist the Global Environmental Monitoring System (GEMS) activities in exposure assessment projects around the world. EPA serves as the U.S. focal point for the UNEP International Register of Potentially Toxic Chemicals (IRPTC). In that capacity, the Agency distributes the *IRPTC Bulletin* within the U.S. and responds to international requests for information on specific chemicals.

EPA also is an active participant in current UNEP efforts to develop an international framework convention for protecting stratospheric ozone. This activity is covered both by TSCA and the Clean Air Act.

EPA prepared for its annual bilateral consultation with the Commission of the European Communities in October of 1982. Agenda items for this meeting include issues of mutual concern in the areas of new and existing chemicals under TSCA and the Sixth Amendment of the European Economic Community's Directive in Classification, Packaging, and Labelling of Dangerous Substances.

Also in FY'82, EPA took further steps to implement its responsibilities under the Multi-lateral Trade Negotiation Agreement on Technical Barriers to Trade, as incorporated in the 1979 U.S. Trade Agreements Act. EPA is required to provide adequate periods for international comment on trade-sensitive regulations, to honor the U.S. commitment to "transparency" in decision-making, and to avoid any activities which may create technical barriers to trade. EPA has reviewed its procedures for developing standards which may be subject to the Trade Agreements Act, and is satisfied that all activities under TSCA are in full compliance.

II. New Chemicals

Program Status

Congress instructed EPA, in Section 5 of TSCA, to review new chemicals. Manufacturers must notify the Agency at least ninety days before they begin manufacturing a new chemical. This notification is called a premanufacture notification or PMN. Since July 1979, EPA has reviewed more than 1,700 new chemicals with the rate of submission increasing dramatically each year. In FY'82 alone, 839 were received — nearly one half the cumulative total received to date.

Section 5(e) of TSCA authorizes EPA to regulate a new chemical, pending the development of information that is needed to make a reasoned evaluation of its health and environmental effects. Such an action is taken if a chemical presents unreasonable risks or is manufactured in substantial quantities and results in substantial environmental release or human exposure. Section 5(f) authorizes EPA to issue rules, or orders, controlling the manufacture, processing, or distribution of individual new chemicals in commerce that present unreasonable risks. During the 1982 fiscal year, five new chemicals were subject to the development of either a 5(e) or a 5(f) order. In one case, a company entered into a Consent Order with EPA agreeing not to manufacture the two new chemicals until certain data was developed. In the remaining cases, the companies withdrew their PMN manufacturing proposals.

Informal negotiations with companies submitting PMNs to obtain their agreement to undertake testing of chemicals or otherwise voluntarily control expected risks have been highly successful. In instances where EPA has identified specific concerns — particularly about detailed circumstances of exposure or use — manufactures have, for the most part, been willing to provide additional information. In addition, companies have often taken steps at the Agency's request to develop fur-

ther data or to institute exposure controls. During FY'82, this approach resulted in twenty-nine cases of voluntary actions. (See Table 1.)

During the early half of the fiscal year, an intensive review of the new chemical program was undertaken by senior program management. This study led to a change in the thrust of the program. Experience showed that greater emphasis could be placed on exemptions coupled with strong so-called follow-up activities. For this reason, the program is moving to develop a more comprehensive new chemicals program, reducing the notice burden on new chemicals of low concern (exemptions) and more effectively encouraging the development of health and environmental effects data on other chemicals as their uses and exposure expand (follow-up). These two elements of the comprehensive new chemicals program are described below.

Table 1

Summary of New Chemical Actions
October 1, 1981 - September 30, 1982

Actions	No. PMNs in FY'82	Aggregate Total Since Beginning (mid-1979)
Valid PMNs Received	839	1,711
Notice of Commencement of Manufacture	92	536
Voluntary Testing in Response to EPA Concerns	5	15
Voluntary Control Actions by Submitters	15	30
PMNs Suspended in Response to EPA Concerns	9	14
PMNs Withdrawn	3	15
Section 5(e) Orders Issued	4	11
Section 5(f) Order Initiated	1	1

Exemptions

The first element of the PMN program is an effective exemption program. Section 5(h)(4) of TSCA authorizes EPA to exempt new chemicals from premanufacture review, if the Agency finds that they will not present an unreasonable risk. Such a finding then allows EPA to concentrate its resources on those new chemicals the Agency considers to have a potential for unreasonable risk. This exemption policy also encourages chemical innovation in low-risk chemicals; allows the more rapid introduction of new low-risk chemicals into manufacture after EPA review is completed where no concerns are raised; and reduces regulatory burdens on manufacturers of new chemicals without reducing protection to public health or the environment.

This exemption policy was begun in FY'82 with a final rule for some instant photographic chemicals. This rule, published on June 4, 1982, exempted manufacturers of certain chemicals used in instant photographic and peel-apart film articles. The rule establishes workplace exposure limits and control guidelines.

Although the Agency began its exemption program with a narrow class of chemicals, it is directing its efforts toward identifying broader classes of ow-risk chemicals. Exemption proposals for certain site-limited intermediate chemicals, low-volume chemicals, and polymers were published for public comment on August 4, 1982. These categories were identified as being of low risk concern after over two years of experience reviewing more than 1,700 PMNs. Under the proposal, most of the chemicals in these categories would undergo an abbreviated Agency review.

The exemption for site-limited intermediate and low-volume chemicals would apply to (1) chemical intermediates – chemicals used in the production of other chemicals – that are used only at the site of manufacture, and (2) chemicals manufactured at volumes of 10,000 kilograms (22,000 pounds) or less per year. Under the proposal, manufacturers would submit an informational notice for EPA review 14 days before manufacture of an exempt chemical. During these 14 days, EPA would review the notice to ensure that all of the requirements of the exemption are met. Chemicals known to be, or reasonably suspected of being, carcinogens or teratogens would be automatically excluded from the exemption; also excluded would be chemicals that might cause other adverse human or environmental effects under anticipated conditions of exposure. In addition, the proposal would require manufacturers to have a qualified expert assess the risks of the chemical and conclude that it would meet the conditions of the exemption before the exemption would be granted.

This proposal also would allow an exemption for chemicals produced at 1,000 kilograms (2,200 pounds) per year or less without review by a qualified expert and without any automatic exclusions. EPA would continue to have a 14-day review and

III. Existing Chemicals

would prohibit chemicals from manufacture under the exemption if the review indicated that they had potential for adverse human or environmental effects.

Under the proposal, manufacturers of polymers that the Agency has identified as posing an especially low hazard would only be required to notify EPA when manufacture began. As a class, polymers are substances that, because of inherent chemical properties, are not likely to be absorbed into living tissue or to be biologically active. Manufacturers of other potentially exempt polymers not identified by EPA as a low hazard would be required to submit a brief notice to EPA 14 days before manufacture. EPA would have the authority to require health and environmental effects data on these polymers or otherwise to require the submission of regular PMNs if it found that they might present an unreasonable risk.

Follow-up

The second element complementing the PMN review program is an effective strategy to monitor new chemicals that might be of concern as their uses change or volumes increase. EPA proposes to employ – whenever necessary – any one of several strong follow-up tools to re-review any new chemicals that may cause unreasonable risks in the future if manufactured, processed, distributed or used outside of the original conditions of review.

During FY'82, the Agency made progress in developing significant new use rules (SNURs) under Section 5 and reporting requirements under Section 8 for follow-up. SNURs can be used at the end of the ninety-day premanufacture review period. They require in specific cases, that the manufacturer notify EPA before a chemical is produced for a significant new use. Section 8(a) of TSCA could be used at any time, on any chemical, to require manufacturers, processors, and importers of that chemical to submit production, use and exposure data. This information, when combined with Agency projections, will allow the EPA to decide whether a chemical should be considered for any type of voluntary or mandatory control action or whether additional chemical testing is necessary.

A third follow-up tool was identified and will be considered for use in specific situations. EPA may, beginning at the end of the ninety-day premanufacture review period, require that when commercialization reaches a certain point, manufacturers must submit additional test data. This is a "delayed trigger" for a TSCA Section 5(e) action.

Chemical Testing

EPA's chemical testing program is one of the focal points for the development and accumulation of test data under TSCA. Test data retrieved under the authority of TSCA Section 4 will narrow the gap of scientific knowledge for other regulatory agencies as well as for the EPA. Section 4 of TSCA gives EPA the authority to require manufacturers and processors of a designated chemical to test for certain adverse health or environmental effects. Section 4 also established an Interagency Testing Committee (ITC) which designates chemicals for priority testing consideration. The ITC's list of designations is limited to 50 chemicals at any one time, although additional chemicals may be added as EPA responds to previous designations. The Committee under the Act must consider revising its list every six months. EPA must respond within one year to each designation by initiating rulemaking to require testing or giving reasons for not doing so.

Program Status. The EPA was sued in 1979 for failure to respond to ITC designations within the statutory deadline of one year. The result of the suit was a court order putting EPA on a three-year schedule to respond to the backlog of chemicals from ITC lists 1 through 6. By the end of FY'82, the Agency had met the first year of the court schedule and reduced this backlog from 37 to 26 chemicals. At the same time, EPA executed its statutory responsibilities of responding within one year for new designations on ITC lists 7 and 8.

During this fiscal year, EPA implemented the concept of negotiating testing agreements with industry as an alternative to rulemaking in appropriate cases. In order to be acceptable, the industry generally must agree, prior to EPA's statutory or court-ordered deadlines, to perform the testing recommended by the ITC to the extent EPA has determined that the testing is ap-

propriate under the criteria of §4 of TSCA. The negotiated agreement includes a description of testing to be performed, preferred test protocols, and a schedule for completion. The negotiation process also always provides opportunities for public comment on the agreement and on the testing program.

The greatest benefit of the negotiated testing agreement approach is the potential for getting testing under way far more quickly than through the time-consuming rulemaking process, which involves proposal, public comment, possible reproposal, and final rule. The negotiated testing approach can lead to initiation of testing within one-and-one-half years after ITC designation, whereas rulemaking will average from two-and-one-half to three years after ITC designation. EPA has already received some test data from testing agreements negotiated in January and April 1982 for chlorinated paraffins and for 2-chlorotoluene, respectively. The speed-up of testing and the reduced adversarial relationship are other important public benefits. The Agency still retains its rulemaking perogatives, should they be needed.

In FY 1982, EPA negotiated four testing agreements, issued seven decisions not to test (seven chemical substances or categories), published one proposed rule and two advanced notices of proposed rulemaking. (See Table 2.)

Information Reporting. To enhance the Agency's ability to make a decision concerning the need for chemical testing or control activities, EPA issued two final rules to gather much needed information from industry.

On June 22, 1982, EPA published a final TSCA Section 8(a) Preliminary Assessment Reporting Rule. This rule requires manufacturers to report production, use, and exposure data, which are crucially important to the Agency's activity concerning the ITC-designations as well as other chemicals. These data will aid the Agency in deciding whether testing is necessary. When combined with the results of testing, these data also will allow the Agency to link chemical-specific hazard and exposure information in making any future control decisions. In addition to the ITC chemicals, the list of 250 chemicals subject to the above final Preliminary Assessment Reporting Rule contains certain chemicals brought to the Agency's attention under Section 8(e) of TSCA.

Table 2

Responses to Interagency Testing Committee (ITC) Designations

Date	Chemical/Category	Action	ITC List
10/30/81	Fluoroalkenes	Advanced notice of proposed rulemaking: testing requirements	7
10/30/81	Alkyl Phthalates	Test agreement negotiated with industry; preliminary decision not to require testing (final decision 1/5/82)	1
10/30/81	Benzyl Butyl Phthalates	Test agreement negotiated with industry; preliminary decision not to require testing (final decision 1/5/82)	7
11/2/81	Butyl Glycolyl Butyl Phthalates	Decision not to test: non-TSCA jurisdiction; FDA responsibility under FDCA	7
11/2/81	Polychlorinated terphenyls	Decision not to test: all production and importation has ceased; no exposure	2
	Chlorinated naphthalenes	Decision not to test: U.S. production has ceased, only minor importation; extremely limited exposure	2
11/5/81	Benzidine-based dyes; o-Tolidine dyes; o-Dianisidine dyes	Decision not to test: ongoing extensive government and industry testing	5 5 5
1/8/82	Chlorinated Paraffins	Test agreement negotiated with industry; decision not to require testing	1
1/8/82	Phenylenediamines	Advance notice of proposed rulemaking: testing requirements	6
4/28/82	2-Chlorotoluene	Test agreement negotiated with industry; decision not to require testing	8
4/29/82	Diethylenenetriamine (DETA)	Proposed testing requirements	8
4/28/82	Hexachloroethane (HCE)	Decision not to test: environmental effects testing not needed due to small quantities released	8

The final 8(a) rule was accompanied by three proposed amendments. The first would allow the Agency to require supplemental information from companies that further process these manufactured products. This additional information would be requested if EPA received insufficient information from the original manufacturers' reports. Another proposed amendment would add about 50 chemicals to the rule. These chemicals were designated by the ITC after the final rule had been proposed. The third amendment would provide for automatic reporting of information following future ITC designations.

The second final reporting rule, under Section 8(d) of TSCA, was published on September 2, 1982. This rule requires manufacturers and processors to submit data from unpublished health and safety studies (with certain exceptions) on the first five ITC chemical priority lists and on all new ITC designations beginning with the Eleventh Report. Reports on the Sixth through the Tenth lists of chemicals were only proposed and will not be made final in FY'83. This final regulation will provide EPA with access to data on health and safety studies that were previously unobtainable. This information will aid the Agency in making decisions on the need for testing under Section 4 as well as for possible regulatory actions under Section 6.

Test Guidelines. Section 4 of TSCA also requires the development and annual review of test standards and guidelines. In March 1982 the Agency announced its policy to issue test protocols as guidelines rather than as regulations. This approach was taken to reduce unnecessary rigidity in testing methodologies. Good Laboratory Practices will continue to be issued as requirements, however.

The Agency exceeded its FY 1982 goal of 30 by developing a total of 80 test guidelines, representing 96 individual test methodologies. These were forwarded to the National Technical Information Service (NTIS) to be made available to the public. The methodologies covered environmental and health effects and chemical fate testing. These guidelines were harmonized with those developed by the International Organization for Economic Cooperation and Development (OECD). The Agency will review the guidelines annually for necessary updating and will continue to develop further needed testing guidelines and continuing its harmonization as appropriate.

Reimbursement. To ensure fair distribution of cost among chemical manufacturers connected with performing required testing under Section 4, EPA proposed a Data Reimbursement Rule on June 4, 1982. The proposal is designed to resolve issues among manufacturers without government intervention to the extent feasible. The proposal encourages the private and voluntary allocation of costs among those subject to a test rule and provides a framework for the efficient resolution of disputes that the parties choose to refer to EPA, because they cannot come to a settlement. The proposed rule incorporates the procedures of the American Arbitration Association. The officer hearing these disputes and rendering the initial cost allocation decision would be appointed from the private sector rather than from the Federal.

Small Business Initiatives

During the year, the TSCA program accelerated its efforts to provide assistance and relief, as necessary, to small companies subject to TSCA authorities. For example, on June 23, 1982, the Agency published a proposed rule that would define which chemical manufacturers are "small manufacturers" and would, therefore, be exempt from most future reporting and recordkeeping rules under Section 8(a) of TSCA. Ninety-nine percent of industrial production will still be covered by reporting requirements since most chemical production is concentrated in large firms. The proposed exemption would, therefore, reduce the paperwork burden on small chemical manufacturers, without significantly affecting the accuracy of the Section 8(a) production data reported to EPA.

There are two proposed small manufacturer exemption standards in the rule. A company will qualify as "small" if it meets either standard. By the first standard, a chemical manufacturer will qualify as small if the total annual sales of all sites owned or controlled by its foreign or domestic parent company are less than $30 million. However, if such a manufacturer annually produces over 45,000 kilograms (100,000 pounds) of a particular chemical at a particular plant site, that manufacturer will not qualify as small with regard to that chemical at that plant site.

By the second standard, a chemical manufacturer will qualify as small if total annual sales of all sites owned or controlled by its foreign or domestic parent company are less than $3 million, regardless of the quantity of chemicals produced by that firm.

Existing Chemical Strategy

During the 1982 fiscal year, EPA redesigned its existing chemicals evaluation program under TSCA to give it better focus. The goal of this program is to reduce unreasonable risk of injury to health or the environment from chemicals already in commerce. The thrust of the new program initiated in FY'82 is to formalize a

scheduled evaluation process, to focus resources first on chemicals of major concern, to take action quickly, and to avoid long lists of chemicals awaiting disposition.

As with other TSCA activities, negotiated solutions to resolve problems with existing chemicals will be pursued if appropriate. However, TSCA Section 6 rules will be promulgated as needed to reduce unreasonable risks. Risk identification activities will first deal with problems identified through statutory mechanisms, such as substantial risk notices (Section 8(e)) and requirements to regulate PCBs (Section 6(e)), citizen petitions (Section 21), and data developed from test rules or negotiated agreements (Section 4).

Illustrative of the success potential of nonregulatory approaches to controlling risks has been the use of the "substantial risk" information reporting provision, Section 8(e) of TSCA. Under this provision, chemical manufacturers, processors, and distributors are required immediately to notify EPA when they obtain any new information that reasonably supports a conclusion that a chemical poses a substantial risk of injury to health or the environment. In FY'82, EPA evaluated 45 such notices of substantial risk.

The Agency also receives notices submitted on a "For Your Information (FYI)" basis from those who have risk-related information that does not fit Section 8(e) criteria, but feel that it needs to be brought to the Agency's attention. Such FYI submissions totaled 76 in FY'82.

With on-going and specific Agency encouragement and through informal negotiations, more and more companies are voluntarily controlling uses of and limiting exposures to toxic chemicals in a variety of ways. Actions which range from worker notification, to process/handling changes, to discontinuing production have been brought to EPA's attention by both TSCA Section 8(e) and FYI submissions.

Polychlorinated Biphenyls (PCBs)

Section 6(e) of TSCA generally bans the manufacture (including importation), processing, distribution in commerce, and use of PCBs. Section 6(e) also requires EPA to issue regulations regarding disposal and labeling of materials containing PCBs. Accordingly, in February 1978, EPA issued a rule regulating the disposal and marking of PCBs. This rule required the marking of many PCB items still in service and set up a system for the proper disposal of PCBs. On May 31, 1979, EPA issued a PCB Rule that mitigated the total ban on the manufacture, processing, distribution in commerce, and use of PCBs, by allowing certain exceptions.

Shortly after this PCB Ban Rule was issued, the Environmental Defense Fund (EDF) challenged the rule's validity before the U.S. Court of Appeals for the District of Columbia Circuit. EDF sought review of this rule on three points: (1) EDF challenged the determination by EPA that certain commercial uses of PCBs are "totally enclosed," and, therefore, exempt from regulation under the Act; (2) EDF claimed that EPA acted contrary to law when it limited the applicability of the statutory bans on manufacture, processing, distribution in commerce, and use of PCBs to materials containing concentrations of PCBs greater than 50 ppm; and (3) EDF challenged the decision by EPA to authorize the continued use of 11 non-totally enclosed uses of PCBs.

On October 30, 1980, the Court ruled in favor of EDF on the first two challenges. Subsequent negotiation by the parties resulted in orders by the Court allowing EPA time to publish revised PCB regulations. These rules were to address use of PCBs in electrical equipment by August 19, 1982 and manufacture, processing, distribution and use of PCBs in closed manufacturing processes and controlled waste-manufacturing processes by October 13, 1982. In addition, by November 1, 1982, EPA was required to submit to the Court a plan describing future regulatory action on uncontrolled PCBs processes.

The rule governing use of PCBs in electrical equipment was signed by the Administrator on August 18, 1982. This rule allows the use of certain electrical equipment containing PCBs to continue under specified conditions because the Agency has concluded that the uses will not present an unreasonable risk. The rule prohibits the use of PCBs in transformers and electromagnets (with a PCB concentration of 500 ppm or greater) posing an exposure risk to food or feed after October 1, 1985; and the rule requires a weekly inspection of this equipment for leaks until that date. Other provisions include:

- A requirement for a quarterly inspection of other PCB transformers (for their remaining useful life);
- A requirement to maintain records of inspection/maintenance for at least 3 years after disposing of PCB transformers;
- An authorization for the use of large PCB capacitors that are located in contained and restricted access installations or restricted access electrical substations for the remainder of their useful lives; and
- A prohibition on the use of all other large PCB capacitors after October 1, 1988.

On October 12, 1982, the Administrator signed a second rule. This regulation excludes from the 1979 ban two types of processes that manufacture PCBs as by-products or impurities. First, PCBs released from the processes into the air, water, or waste products are excluded if they do not exceed limits stated in the rule. These limits represent the lowest levels able

to be practically quantified. Other processes may be excluded from the statutory ban if the wastes exceed the limits, provided such wastes are disposed of in an EPA-approved manner, and as long as PCBs released into the air, water, and products are below the limits stated in the rule.

Asbestos

During the 1982 fiscal year, EPA brought several asbestos activities to fruition. Two rulemaking actions were completed, and steps were taken to better coordinate the Federal government's asbestos investigations and regulatory programs.

One important rulemaking action was to inform the nation's school population of the presence of any friable (crumbling) asbestos-containing materials. On May 27, 1982, EPA published the final "Asbestos-in-Schools" rule, which requires public and private elementary and secondary schools to identify friable asbestos-containing building materials, to maintain records of their analysis and the location of friable materials, and to notify school employees and parents when friable asbestos is found.

This rule is complemented by EPA's Technical Assistance Program (TAP). The TAP, available through the EPA Regional offices, provides guidance to aid schools in investigating the presence of asbestos in their buildings, and in determining whether abatement actions are necessary.

One of the primary obstacles to additional asbestos investigations is the lack of needed exposure and production data. To this end a second major asbestos rulemaking was published on July 30, 1982, under Section 8(a) of TSCA. The rule requires that asbestos producers, importers, and processors report certain information about their industrial and commercial activities. Specifically, this reporting will include the following information: identification of producers, importers, and processors and their asbestos-containing products; amounts mined, consumed, and imported; summaries of monitoring data in the workplace; identification of plant sites and estimates of site emissions; and amounts of wastes generated and methods of disposal.

The regulation requires information to be submitted to EPA in two phases beginning October 30, 1982. The information gathered will provide a current data base to identify unreasonable risks from asbestos exposure and for developing initiatives to protect public health. The rule will support investigations by the EPA and other Federal agencies.

In mid-1982, EPA initiated the formation of both a Federal Asbestos Task Force* and an EPA Asbestos Task Group to work toward developing a unified Federal approach to asbestos regulation and to coordinate the future actions of participating Federal agencies. This coordinated approach demonstrates the Agency's commitment to the dual objectives of protecting the public with cost-effective, nonduplicative, and consistent programs.

Dioxins

TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin) is an undesirable contaminant formed during the manufacture of certain substances. TCDD, commonly referred to as dioxin, is highly toxic and is found to be carcinogenic in laboratory animals; it has other significant adverse health effects as well.

On May 12, 1980, EPA promulgated a rule under Section 6 of TSCA prohibiting Vertac Chemical Company from disposing of its wastes containing TCDD stored at its Jacksonville, Arkansas facility. The rule also requires that any other persons planning to dispose of TCDD-containing wastes notify the Assistant Administrator for the Office of Pesticides and Toxic Substances 60 days prior to their intended disposal.

The existing rule is and was intended to be, a short-term solution to a long-term problem. It also provided EPA with the opportunity to review plans by other companies to dispose of TCDD-containing wastes and to stop that disposal, if necessary.

In January 1982, EPA published in the *Federal Register* an Advanced Notice of Proposed Rulemaking (ANPR) to announce its intent to review the dioxin rule. The ANPR also solicited a proposal from Vertac about how to dispose of its wastes and comments from the general public about potential methods for disposing of any TCDD-contaminated wastes.

Two weeks after publishing the ANPR, EPA, the State of Arkansas, and Vertac entered into a Consent Decree that controls the management of TCDD-contaminated wastes and other site conditions at the Vertac facility in Jacksonville, Arkansas. This Consent Decree requires a number of studies to be conducted in order to determine existing conditions in and around Vertac's facility. It also requires that Vertac submit both an inventory of the wastes stored on site and a proposal for managing those wastes. The Consent Decree requires that Vertac make its "best efforts" to reduce the volume of stored wastes and to report to EPA every six months for five years about its progress in reducing waste volume. The Consent Decree specifies that any applicable regulation promulgated by various governmental authorities takes precedence over the Decree.

*Consumer Product Safety Commission, Occupational Safety and Health Administration, and Environmental Protection Agency with the National Institute of Occupational Safety and Health, Mine Safety and Health Administration, Food and Drug Administration, National Institute of Environmental Health Sciences, National Cancer Institute serving as associate members.

Formaldehyde

In December 1981, the Chemical Industry Institute of Toxicology published the final report of their 24-month inhalation study in which rats exposed to formaldehyde developed nasal cancer. The preliminary results of this study, coupled with formaldehyde's widespread exposure, brought formaldehyde to the attention of EPA for investigation under TSCA. After review of the available data, the Agency concluded that formaldehyde is a carcinogen in the rat by the inhalation route and possibly also in the mouse by the same route. It is also presumed that formaldehyde may, in theory, pose a risk of cancer to humans. However, analysis of exposure scenarios led to the conclusion that cancer risks posed by formaldehyde exposures under EPA's jurisdiction were low.

Because some potential health effects of formaldehyde are still of concern, EPA is working to identify needed information and achieve consensus for filling any data gaps. On June 30, 1982, EPA signed an Interagency Agreement with the National Center for Toxicological Research, a Federal facility co-funded by EPA and the Food and Drug Administration, to (1) establish expert review panels with scientists from government, academia, and industry that will conside: data on exposure, risk estimation, toxicology, and epidemiology; (2) create an information clearinghouse on existing and new scientific data; and (3) hold a scientific consensus workshop to agree on future actions to improve data on formaldehyde, and to publish peer review workshop proceedings. EPA believes that this action will bring concerns over formaldehyde's health effects into better balance.

In addition under the TSCA program, the Agency is funding a large-scale epidemiology study designed to fill the gaps that have been identified in the existing epidemiology data base.

Chlorofluorocarbons (CFCs)

Stratospheric pollution arising from human activities may lead to a decrease in stratospheric ozone, which could lead to an increase in ultraviolet radiation from the sun at the earth's surface. Pollutants thought to affect the ozone (creating/destroying equilibrium) include: (1) chlorofluorocarbons (CFCs) and certain other halogenated hydrocarbons (e.g., methyl chloroform, carbon tetrachloride, etc.); (2) nitrogen oxide emissions (NO_x) from sub- and supersonic aircraft; (3) nitrous oxide (N_2O) from agricultural practices and high-temperature combustion; (4) carbon dioxide resulting from the combustion of fossil fuels and deforestation; and (5) methane (CH_4) released from the biosphere. Ozone blocks a portion of the ultraviolet radiation (UV-B) emitted from the sun. UV-B is known to have certain deleterious biological effects. However, the type and magnitude of stratospheric modification due to these pollutants remain uncertain.

The United States has been participating in and supporting the international activities related to the ozone issue. For example, the United Nations Environment Program (UNEP) activities related to stratospheric ozone are increasing. The U.S. is participating in the drafting of the UNEP framework convention to protect stratospheric ozone. The convention, once completed, would formalize international cooperation in the science, monitoring, and exchange of information.

EPA is also pursuing additional research on the depletion issue with other Federal agencies, industry, and academia. During FY'82, the Agency initiated a number of activities under TSCA to increase its information base in this area. EPA is currently contributing to the funding of further atmospheric modeling at the Lawrence Livermore Laboratory at a total of $300,000 over a three-year period. In the spring of 1982, EPA signed an Interagency Agreement with the National Oceanic and Atmospheric Administration (NOAA), with contributions from the World Meteorological Organization and industry, to establish six automated land-based ozone monitoring stations (Umkehr system) throughout the world.

In addition to its domestic research and international efforts, EPA is continuing to assess the need for further regulatory initiatives as more data become available and to "fine tune" its 1978 ban on nonessential uses of CFCs as aerosol propellants. In FY'82, the Agency responded to three petitions seeking exemptions to this rulemaking, citing essential uses. The first two petitions, for which exemptions were granted January 5, 1982, include the use for pharmaceutical rotary tablet press punch lubricants and use in spinnerette release agents.

The former action was based on the fact that there were no available alternatives and the fact that removal could have had an adverse economic impact and a potentially unfavorable health impact on the public. The latter exemption was granted on the basis that substitutes are not available for all uses.

A third petitioner, Virginia Chemicals, Inc., was issued an immediately effective special exemption on June 1, 1982, permitting the limited use until December 31, 1982, of CFCs in time-released insecticide dispensing systems used in treating long-term stored tobacco. The exemption allows the use during the 1982 tobacco infestation season but denies use during all subsequent seasons.

IV. Enforcement

Under Section 16 of TSCA, EPA may levy either civil or criminal penalties for a violation of several sections of the Act. The Agency has developed specific enforcement strategies for implementing regulations under TSCA. These strategies identify and rank possible violations of a particular regulation, identify the tools available for compliance monitoring and how they will be used, provide a formula for determining the application of inspection resources, and establish a policy for determining civil penalties under the regulation.

Civil Enforcement Action. In FY 1982, all but one enforcement action under Section 16 involved alleged violations of the PCB rules. The Agency filed a total of 100 civil complaints during the fiscal year as a result of the PCB inspections; 93 cases were completed; and $475,850 in civil penalties was assessed. Figures for each EPA Region appear in Table 3.

The Agency assessed the largest single penalty, $47,500, against the Electrical Service Company (ESC) of Cincinnati, Ohio. On August 10, 1982, Administrative Law Judge Marvin E. Jones held that ESC had violated the disposal, marking, storage, and recordkeeping requirements of the PCB regulations. The Respondent is appealing the decision to the Administrator.

Criminal Enforcement Actions. Criminal cases must be filed on EPA's behalf in Federal court by the Department of Justice. In FY 1982, two potential criminal cases were referred to the Department of Justice for consideration. Also during the year, the Fourth Circuit Court of Appeals upheld the May 1981 conviction of Mr. Robert E. Ward, of the Ward Transformer Company, for aiding in the illegal dumping of transformer oil contaminated with PCBs on roadsides in North Carolina.

Compliance Actions. The EPA took action to enforce compliance with various TSCA requirements. The EPA, along with five State agencies cooperating under the terms of enforcement grants-in-aid, conducted 2,089 PCB compliance monitoring inspections. Region II issued an administrative civil complaint citing the American Cyanamid Company with violating the substantial risk reporting requirements of TSCA Section 8(e). The Respondent paid a civil penalty of $18,750. The Agency conducted 43 inspections to monitor compliance with the interagency ban on nonessential aerosol uses of CFCs and conducted 32 inspections to determine compliance with the dioxin rule under Section 6. Also, in FY 1982, the Agency inspected 17 firms that failed to meet the deadline for reporting identities of existing chemicals as required under Section 8(b) of TSCA. The inspections were conducted to ensure that substances reported late to the Agency were not, in fact, new chemicals subject to the PMN requirements of Section 5. The Agency also conducted 33 inspections and compliance monitoring reviews of facilities subject to Section 5 requirements.

Program Actions. During FY 1982, EPA developed compliance strategies for enforcing the Section 5(h)(4) instant photographic materials exemption, the Section 6 Asbestos-in-Schools Rule, the Section 6 PCB Interim Measures program, and the Section 8(a) Level-A Reporting Rule; and strengthened existing strategies for Sections 4 and 5. In addition, EPA implemented a cooperative program with the Food and Drug Administration (FDA) for the inspection of food and feed facilities for PCBs.

Pilot cooperative enforcement agreements with five States (California, Connecticut, Maryland, Michigan, and Ohio) continued in FY 1982. These grants will provide data for use by other States in developing their own toxic substances compliance programs.

The Agency began an evaluation of the PCB compliance program in FY 1982. When the evaluation is completed, EPA will be able to revise the current compliance strategy to better target high-risk facilities to achieve maximum environmental results.

The Agency also utilized negotiated compliance agreements to bring a number of firms into compliance with TSCA rules.

Table 3

Administrative Civil Actions Taken Under Section 16 of TSCA for Violations of PCB Regulations Complaints Issued, Cases Completed, and Amounts Assessed (by Region)*

Region	Total No. Complaints Issued FY '79-82	No. Complaints Issued in FY '82	Total No. Cases Completed FY '79-82	No. Cases Completed** in FY '82	Total No. of Cases Pending	Total Civil Penalty Amount Assessed (in $) in FY '82	Total Civil Penalty Amount Assessed (in $) in FY '79-82
I	8	1	7	1	1	0	30,100
II	68	16	46	17	22	92,550	479,300
III	26	15	17	9	9	35,075	81,775
IV	12	3	3	0	9	0	23,525
V	66	25	36	23	31	176,100	278,920
VI	54	14	40	15	13	39,200	142,460
VII	22	6	14	6	8	23,150	49,300
VIII	30	13	24	12	6	65,200	163,300
IX	15	4	10	4	5	30,375	56,675
X	8	2	5	5	3	14,200	14,200
HQ	2	1	1	1	1	0	0
Total	311	100	203	93	108	475,850	1,319,555

*All actions taken involved alleged violations of Section 6 PCB rules.

**Includes cases carried over from FY '80-FY '81.

V. Litigation

Environmental Defense Fund, Inc. v. Environmental Protection Agency (No. 79-1580, D.C. Cir.). In 1979 the Environmental Defense Fund (EDF) petitioned for review of EPA's regulations under TSCA Section 6(e)(2) and (3) governing the manufacture, processing, distribution, and use of polychlorinated biphenyls (PCBs). A decision largely in EDF's favor was issued on October 30, 1980. This decision, and its aftermath, were reported in TSCA annual reports for 1980 and 1981. Developments in this case for 1982 are as follows:

In March 1982, EPA advised the Court of its plans for further action with rspect to the regulation of other PCBs in low concentrations and submitted to the Court a motion to extend the stay of the mandate for such low concentration PCBs until December 1, 1982. EPA reasoned that it had to determine which processes were to be regulated under the October 1982 rule before further action could be planned. The Court granted EPA's request in an April 9, 1982, order. The order required EPA to submit a plan of action to the Court by November 1, 1982.

On August 18, 1982, EPA promulgated a final rule on the use of PCBs in electrical equipment. Petitions for review of that rule have been filed by several parties in the U.S. Court of Appeals for the District of Columbia Circuit and the U.S. Court of Appeals for the Fourth Circuit:

Natural Resources Defense Council, Inc. and *Environmental Defense Fund, v. EPA* (D.C. Cir., No. 82-2045)

American Frozen Food Institute, Inc. v. EPA (4th Cir., No. 82-1790)

The National Electrical Manufacturers Association v. EPA (D.C. Cir., No. 82-2166)

The Edison Electric Institute, The National Rural Electric Cooperative Association, et al., v. EPA (D.C. Cir., No. 82-2198)

EDF also amended its petition for review in the original PCB case.

It is anticipated that all dockets will be consolidated for hearing before one court. Arguments will be filed during FY'83.

In a manner related to the original PCB litigation, the Court Awarded EDF approximately $100,000 in attorney fees under Section 19(d) of TSCA. This was reduced from EDF's original request of approximately $170,000. EDF's claim was based on time expended by its attorneys in prosecuting *EDF v. EPA*, adjusted upward by a factor of 2, under applicable case law, to reflect the quality of representation and the contingent nature of success in the litigation. The Court rejected EDF's upward adjustment but awarded an amount equal to almost the entire amount of attorney fees requested plus an upward adjustment of 17 percent to reflect public benefit resulting from the litigation and delay in receipt of payments. The Court rejected EPA's arguments that EDF was not entitled to an award for:

(1) work performed on issues upon which EDF did not prevail;

(2) work performed on issues raised by industry intervenors; and

(3) work performed in connection with post-decision negotiations.

EPA's petition for rehearing on whether EDF was entitled to an award on issues upon which it did not prevail is still pending.

Warren County v. North Carolina (No. 79-560-CIV-5) and *Twitty v. North Carolina* (No. 80-41-CIV-5) (E.D.N.C.)

These actions were brought by Warren County and private parties against the State of North Carolina and EPA to prevent a tract of land in Warren County from being used as a landfill for the disposal of soil contaminated with polychlorinated biphenyls (PCBs). Plaintiffs had challenged EPA actions on three grounds:

(1) The Region IV Administrator's action in preliminarily approving the landfill site was improper under the Toxic Substances Control Act (TSCA) and applicable regulations;

(2) EPA failed to prepare an Environmental Impact Statement (EIS); and

(3) The landfill would violate a County ordinance prohibiting disposal of PCBs.

On November 27, 1981, the Court decided against the plaintifs on all counts. It deferred to Agency expertise in the highly technical area of PCB landfill approval. In dismissing the charge that EPA failed to file an EIS, the Court cited the long string of cases holding that EPA is not required under its other statutes to file an EIS based on the functional equivalency test. The functional equivalency test holds that where a Federal agency is engaged primarily in an examination of environmental questions and full and adequate consideration of environmental issues are ensured, an EIS is not necessary. This is the first case specifically holding that EPA is not required to file an EIS when it takes action under TSCA.

The most significant aspect of the Court's opinion was the decision that Warren County's ordinance is preempted by the provisions of TSCA regulating disposal of PCBs because it would present an obstacle to the accomplishment of Congress' statutory plan under TSCA.

Warren County and the plaintiffs in Twitty filed notices of appeal with the U.S. Court of Appeals for the Fourth Circuit. Warren County voluntarily dismissed its appeal. Briefs were filed in the Twitty appeal, which was set for oral argument on October 6, 1982.

National Association for the Advancement of Colored People (NAACP) v. Gorsuch, et al. (No. 82-768-CIV-5) (E.D.N.C.)

On July 6, 1982, a NAACP chapter in Warren County, North Carolina filed suit against EPA and the State of North Carolina seeking a preliminary injunction against construction of the PCB landfill which was the subject of the Warren County litigation.

Many of the issues raised in the earlier litigation were raised in this case, but several counts claiming violation of the civil rights of Warren County black residents were new. The complaint alleged violation of 42 U.S.C. §§1981 and 1982 (general prohibitions against abridgement of individual and property rights), 42 U.S.C. §2000d (prohibition against discrimination resulting from Federal grants programs), and denial of individual rights under the 13th Amendment to the U.S. Constitution. The court rejected all plaintiffs' arguments in dismissing the case on August 5, 1982.

Noble Automative Chemical and Oil Co. v. EPA (No. 81-1581) (D.N.J.)

Noble Oil filed suit to enjoin administrative penalty proceedings against it for violations of PCB disposl and marking regulations under TSCA. Noble argued that EPA was acting to enforce regulations which had been invalidated by the U.S. Court of Appeals for the District of Columbia Circuit in *EDF v. EPA, supra.* EPA argued that the D.C. Circuit's opinion did not affect the disposal and marking regulations and filed a motion to dismiss Noble Oil's case. The motions are currently under consideration by the court.

The Scott & Fetzer Co. v. EPA (D.D.C., No. 82-0861)

On April 27, 1982, the Court dismissed a suit filed by the Scott & Fetzer Company challenging an EPA decision of February 8, 1982, allowing Transco, Inc. to distribute in commerce existing stocks of PCB capacitors.

Scott & Fetzer's suit, filed on March 26, 1982, was based on Section 20 of TSCA, which authorizes citizen suits to compel EPA to perform nondiscretionary acts. Scott & Fetzer argued that EPA had failed to perform a nondiscretionary act when it allowed Transco to distribute its capacitors.

In dismissing plaintiff's claim the court held that nondiscretionary acts for purposes of citizen suit provisions in environmental statutes are limited "to a chosen few" mandatory duties; where an official must exercise professional judgment and draw upon his expertise, the act is discretionary. The EPA decision complained of was just such a discretionary act.

Aluminum Company of America v. DuBois, (No. 81-3329, 9th Cir.)

Alcoa's appeal from a judgment in Federal District Court that Section 11(a) of TSCA authorizes EPA to designate contractors as EPA representatives for purposes of performing inspections authorized by statute was dismissed at the request of both parties.

There is nothing further to report on the following cases, which were noted in last year's report:

Olin Corporation v. EPA (No. 79-1437, 4th Cir.)

General Electric Company v. EPA (No. 79-1816, D.C. Cir.)

Aluminum Company of America v. EPA (No. 79-1811, D.C. Cir.)

T. Mitchell Langdon et al. v. James B. Hunt et al. (No. 86-487-CIV-5) (E.D.N.C.)

Dow Chemical Company v. Douglas Costle (Civ. Action No. 79-581, D. Del.)

VI. State Programs

State Programs. Section 28(c) of TSCA authorizes EPA to award grants to States for programs to prevent or eliminate problems created by toxic substances that EPA is unable or unlikely to act on under TSCA. Since 1978, EPA has assisted eight states with the development of 11 toxic substances programs.

On August 28, 1978, EPA announced in the *Federal Register* the availability of $3 million for this Federal assistance program and provided guidance to prospective applicants. The announcement also described a two-cycle award process; approximately half the funds were to be distributed in each cycle. In April 1979, cooperative agreements were signed with Maryland, Michigan, New Jersey, New York, and Wisconsin under the first cycle. In February 1980, cooperative agreements were signed with three States (New Jersey, North Carolina, and Puerto Rico*).

On February 11, 1980, EPA announced in the *Federal Register* the availability of an additional $1.25 million for a third and final cycle in the program. In March 1981, cooperative agreements were signed with four States (Illinois, Maryland, Michigan, and Ohio). However, Ohio decided not to proceed with its project and returned its TSCA grant funds.

Three State cooperative agreement projects have been completed. These projects are the Michigan Critical Materials Program, the New York toxics screening procedure study, and the Wisconsin study of health problems related to formaldehyde in mobile home construction.

The original funds Congress appropriated for this program have been awarded.

*As defined by TSCA, "State" includes any U.S. territory or possession.

Table 4

TSCA Section 28
State Cooperative Agreements Program

State/Department	Project Grant Descriptions and Status	Amount	Grant Period
Illinois Department of Public Health	*Purpose*: Develop an integrated voluntary system detecting morbidity and mortality rates resulting from exposure to toxic substances. *Status*: Wrote and disseminated a brochure and newsletter to State and local health officials and medical professionals to explain the State Environmental Toxicology Program and obtain information on disease clusters and trends in local communities. Follow-up investigations are being conducted by the Department. Mortality information from 1964 to 1981 is being gathered, birth defects data is being compiled and computerized as is the pilot cancer surveillance data from 16 counties.	$475,626	March 81-March 84
Maryland Department of Health and Mental Hygiene	*Purpose*: Develop a computer-based Toxic Substances Registry. *Status*: The registry now contains 800 chemicals, an incidents record, cancer reports, all OSHA violations, and a record of all occupationally related diseases.	$230,963	April 79-April 83
Maryland Department of Health and Mental Hygiene	*Purpose*: Develop a program to assure the safe and effective containment of toxic substances in storage tanks. *Status*: The Ecology and Environment Corporation has been subcontracted to work on this project. Technical studies underway.	$100,000	March 81-March 83
Michigan Department of Natural Resources	*Purpose*: Develop an interdepartmental risk assessment process. *Status*: Many risk assessment models have been reviewed and five major models selected for use by the Departments of Natural Resources, Agriculture and Public Health. Extensive environmental fate data has been gathered on 90 priority chemicals used or discharged in Michigan and 33 chemical assessments have been completed. The Department of Agriculture continues to sample and analyze for PCBs and heavy metals. The Department of Public Health has developed a computerized data system handling the State's occupational Health exposure data.	$532,258	March 81-March 83
Michigan Department of Natural Resources	*Purpose*: Critical Materials Program. *Status*: This project has been completed and the final report is being reviewed.	$504,500	April 79-Sept. 82
New Jersey Department of Environmental Protection	*Purpose*: Set up a toxic substances investigation and integration unit; expand current project monitoring volatile organic compounds in air. *Status*: The Toxic Substances Investigation and Integration Unit has identified and investigated various hazardous waste sites in New Jersey. Cancer and birth defects clusters are being investigated. The mobile monitoring van is completed and is currently operating.	$453,947	April 79-April 83
New Jersey Department of Environmental Protection	*Purpose*: Study movement, distribution and uptake of in-place mercury; monitor emissions of selected toxic substances; assess the ecological effects of water contaminants; establish and operate a Toxic Substances Information Resources Center; conduct a field application study of *in vitro* mutagenesis tests. *Status*: Additional sampling and biota have been collected and analyzed for mercury and other heavy metals. Methods and resources required for sampling and analysis of various environmental emissions from selected groups of facilities have been identified and field tested. Research on the effects of environmental stress in aquatic organisms continues. Summary reports of toxic substances research are prepared along with other educational materials. Waste water samples have been assayed for mutagenic activity using the Ames test.	$794,053	March 80-April 84
New York Department of Environmental Conservation	*Purpose*: Identify, characterize and plan for managing toxic substances. *Status*: New York has submitted a final report which is currently being reviewed.	$348,000	April 79-Nov. 82
North Carolina Office of Natural Resources	*Purpose*: Identify, assess and plan to control toxic substances by profiling substances, identifying sources and level and duration of exposures, and developing a plan to control substances posing an unreasonable risk. *Status*: North Carolina is preparing final report.	$386,000	March 80-Dec. 82
Puerto Rico Environmental Quality Board	*Purpose*: Develop and manage the Commonwealth's toxic substances management strategy; expand an existing public participation/awareness program. *Status*: Developed and sponsored a meeting for the Inter-Agency Advisory Committee on Toxic Substances Control. Prepared a questionnaire on PCBs for the industrial plants in Puerto Rico and planned inspection visits.	$258,394	March 80-March 83
Wisconsin Department of Health and Social Sciences	*Purpose*: Study health problems related to formaldehyde vapors from mobil home construction materials. *Status*: This study is complete and the final report has been submitted.	$202,947	April 79-Sept. 82

Appendix A

Summary/Guide to Information Required by Congress

Sections 30, 28(c), and 9(d) of TSCA require that certain information be reported each year to the President and Congress. To assist readers in locating this information, a summary of each pertinent TSCA action and a reference to a more detailed explanation, within this report, is given here.

Section 30. This section contains the basic requirement for an Annual Report and requests the following information:

(1) **Testing.** No final Section 4 rules for specific chemicals have been issued. However, the Agency has negotiated several testing agreements with industry during FY'82. Without formal rulemaking, industry representatives agree to perform specific testing on designated chemicals and to follow certain test protocols. See Chemical Testing in Section III for additional details and a list of the negotiated agreements.

(2) **Premanufacture Notices (PMNs).** EPA received 839 PMNs during FY'82, bringing the total received since the program's beginning in mid-1979 to 1711. None of these chemicals were subject to rulemaking under Section 4. In approximately 30 cases, voluntary testing or control activities took place in FY'82, while five chemicals were subject to the development of either a 5(e) or 5(f) order. See Section II, Program Status.

(3) **Rules Issued Under Section 6.** A final rule governing use of PCBs in electrical equipment was signed on August 18, 1982. The rule allows the use of certain electrical equipment containing PCBs to continue under specific conditions.

A second final PCB rule was signed October 12, 1982, providing for certain exclusions from the 1979 ban on PCBs. The regulation would exclude processes that manufacture PCBs as by-products and impurities as long as PCBs released from the processes into the air, water, or waste products do not exceed limits stated in the rule. Discussion of the two rulemakings is contained in Section III, PCBs.

An ANPRM concerning dioxin wastes was published January 5, 1982. The notice solicited comments about potential methods for disposing of TCDD-contaminated wastes. See Section III, Dioxin.

A final rule, published May 27, 1982, requires public and private elementary and secondary schools to identify friable asbestos-containing building materials, to maintain records of their analyses and the location of friable materials, and to notify school employees and parents when friable asbestos is found. See Section III, Asbestos, for discussion of rule and asbestos program.

(4) **Judicial Actions Under TSCA and Administrative Actions Under Section 16.** All judicial actions concern PCBs. In FY'82, one suit was filed, four petitions to review rulemaking were filed, two suits were dismissed and six cases are pending. See Section V, Litigation, for details.

A total of 93 PCB civil enforcement cases were completed in FY'82. One civil case involving compliance with Section 8(e) of TSCA was also completed. A total of 108 PCB cases are pending. See full discussion in Section IV, Enforcement.

(5) **Major Problems.** No major problems were encountered in FY'82 in administering TSCA.

(6) **Recommended Legislation.** No legislative changes are sought at this time.

Section 28(c). This section requires a report on grants to States during the year. Three State cooperative agreement projects were completed in FY'82. These were undertaken by Michigan, New York and Wisconsin. Eight additional State grants are due to be completed in 1983 and 1984. See description of projects in Section VI, State Programs.

Section 9(d). This section requires that EPA's efforts to coordinate its TSCA activities with related activities of other Federal agencies be reported annually. During FY'82, EPA entered into several formal and informal agreements with other Federal government programs concerning specific chemical activities. These include a Federal Asbestos Task Force (OSHA, CPSC, EPA as charter members), stratospheric monitoring (NOAA, EPA), PCBs in food (FDA, EPA), information development on formaldehyde (NCTR, EPA), information exchange under Section 8(e), as well as work with several international organizations. Details on these activities appear in the appropriate sections of this report.

Appendix B

FY'82 Chronology of Major TSCA Actions

Section of Law	Description	Date
4(a)	For listing of testing decisions see Table 2, Pgs. 10 & 11	
4(b)	Change in Test Standards Policy and Test Rule Development Process	3/26/82
4(c)	TSCA Data Reimbursement (Proposed Rule)	6/4/82
5(e)	Order; Ban pending development of additional data on two chemical dyes	10/9/81
5(e)	Consent Order; Prohibit for consumer use pending development of test data on two PMN chemicals	9/10/82
5(h)(4)	Premanufacture Notification; Exemption for Chemicals Used in or for Manufacture or Processing of Instant Photographic and Peel-Apart Film Articles (Final Rule)	6/1/82 (Proposed 11/3/81)
5(h)(4)	Premanufacture Notification; Exemption for Site-Limited Intermediate Chemical Substances and Chemical Substances Manufactured in Quantities of 10,000kg or Less Per Year (Proposed Rule)	8/4/82
5(h)(4)	Premanufacture Notification; Exemption for Polymers (Proposed Rule)	8/4/82
6(a)	Fully Halogenated Chlorofluoroalkanes; Exemption	1/5/82
6(a)	Fully Halogenated Chlorofluoroalkanes; Exemption, Spinnerette Release Agents	1/5/82
6(a)	Tetrachlorodibenzo-P-Dioxin; Reevaluation of Disposal Prohibition (ANPR)	1/5/82
6(a)	Friable Asbestos-Containing Materials in Schools; Identification and Notification (Final Rule)	5/27/82
6(a)	Fully Halogenated Chlorofluoroalkanes; Temporary Special Exemption for Automatic Timed-Released Insecticide Dispensing Systems Used in Storage of Tobacco	6/1/82
6(a)	Fully Halogenated Chlorofluoroalkanes; Denial of Exemption for Use of Chlorofluorocarbons in Automatic Timed-Release Insecticide Dispensing Systems Used in Storage of Tobacco	6/1/82
6(e)	Polychlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution, and Use in Closed and Controlled Waste Manufactured Processes (Proposed Rule)	6/8/82
6(e)	Polychlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution Commerce and Use Prohibitions; Use in Electrical Equipment (Final Rule)	8/25/82 (Proposed 4/23/82)
8(a)	Chemical Information Rules; Manufacturers Reporting Preliminary Assessment Information (Final Rule)	6/22/82
8(a)	Small Manufacturer Exemption Standards; Reporting and Recordkeeping Requirements (Proposed Rule)	6/23/82
8(a)	Asbestos Information Reporting (Final Rule)	7/30/82
8(d)	Data Reporting; Submission of Lists and Copies of Health and Safety Studies (Final Rule)	9/2/82